PATENT
071949-1328

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kenneth F. Buechler
Title:	DIAGNOSTIC DEVICES AND APPARATUS FOR THE CONTROLLED MOVEMENT OF REAGENTS WITHOUT MEMBRANES
Appl. No.:	10/697,351
Filing Date:	10/29/2003
Art Unit:	1743
Examiner:	Alexander, Lyle
Confirmation No.	7522

REPLY BRIEF

Mail Stop Appeal Brief - Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Examiner's Answer mailed August 17, 2007 Applicants (herein, "Appellants") submit this Reply Brief regarding the Final Rejection of claims 1 and 3-7, which corresponds to all claims pending in the application. This Appeal Brief is accompanied by the requisite fee set forth in 37 C.F.R. § 1.17(f). If this fee is incorrect or if any additional fees are due in this regard, please charge or credit our Deposit Account No. 19-0741 for the appropriate amount.

Table of Contents

Table of Publications

CASES

SECONDARY AUTHORITY

Status of Claims

A. Claim 2 has been cancelled.

B. Claims 1 and 3-7 are pending in the application.

C. Claims 1 and 3-7 are the subject of this appeal.

D. The Examiner acknowledges that the terminal disclaimers submitted by Appellant render moot the obviousness-type double patenting rejection of claims 1, 2, 6 and 7 over U.S. Patents 5,458,852; 5,885,527; 6,019,944; 6,271,040; and 6,905,882. Examiner's Answer, page 7, first paragraph of Response to Argument. Appellant notes that claim 2 is listed in the rejection apparently in error, as claim 2 is not pending in the present application.

E. The Examiner acknowledges that the terminal disclaimers submitted by Appellant renders moot the obviousness-type double patenting rejection of claims 1-7 over U.S. Patents 6,767,510; and 6,156,270. Examiner's Answer, page 7, first paragraph of Response to Argument. Appellant notes that claim 2 is listed in the rejection apparently in error, as claim 2 is not pending in the present application.

F. Claims 1-7 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over U.S. Patent Applications 10/792,258 and 11/022,297. Appellant notes that claim 2 is listed in the rejection apparently in error, as claim 2 is not pending in the present application.

While the Examiner correctly states that these rejections are not being appealed, Appellants note that no terminal disclaimer is procedurally required in a case where the provisional rejection involves two pending applications and where the rejection is the sole remaining issue in the case. See MPEP 804 (I)(B) (The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications."). Because of the provisional nature of the rejections, no response is required of Appellant at this time.

In the event that other rejections of the present claims are successfully overcome on appeal, the current obviousness-type double patenting rejection would then be the sole remaining

rejection, and withdrawal of the instant provisional rejection would be appropriate. Thus, this rejection was not addressed below in the Appeal Brief.

G. Claims 1 and 3-7 stand finally rejected under 35 U.S.C. §112, second paragraph, as allegedly failing to satisfy the definiteness requirement. The Examiner states that the rejections have been partially overcome, and are partially maintained. Examiner's Answer, paragraph bridging pages 7 and 8 and first two complete paragraphs of page 8.

H. Claims 1 and 3-5 and 7 stand finally rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Findlay *et al.*, U.S. Patent 5,514,550.[1] The inclusion of claim 6 in this rejection has apparently been withdrawn in view of a new ground of rejection under 35 U.S.C. §103(a), discussed below.

I. Claims 1 and 3-5 and 7 stand finally rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Wu, U.S. Patent 5,387,510.[2] The inclusion of claim 6 in this rejection has apparently been withdrawn in view of a new ground of rejection under 35 U.S.C. §103(a), discussed below.

J. The Examiner has introduced a new ground of rejection of claim 5 under 35 U.S.C. §103(a), as allegedly being obvious over Findlay *et al.*, U.S. Patent 5,514,550 or Wu, U.S. Patent 5,387,510 in view of Oosta *et al.*, U.S. Patent 5,478,751. As discussed hereinafter, Appellant believes that the rejection is intended to address claim 6, not claim 5.

---

[1] The Examiner asserts that the effective date of the preset claims should be July 11, 2000. Appellant respectfully disagrees. Based on its earliest priority date of February 3, 1989, Appellant assumes the Examiner would maintain the anticipation rejection based on Findlay *et al.* under 35 U.S.C. § 102(e), regardless of the present claims being entitled to an earlier priority date.

While the question of priority apparently does not affect this rejection at issue, the question does affect the new ground of rejection entered by the Examiner based in part on Oosta *et al.*, U.S. Patent 5,478,751, and is addressed later in this Reply Brief.

[2] Likewise, based on its earliest priority date of October 2, 1991, Appellant assumes the Examiner would maintain the anticipation rejection based on Wu under 35 U.S.C. § 102(e).

Grounds for Rejection to be Reviewed on Appeal

1. The rejection of claim 6 as allegedly being indefinite under 35 U.S.C. §112, second paragraph, with regard to the phrase "forms a capillary space between said nonporous surface and a second surface spaced at a capillary forming distance from said nonporous surface."

2. The rejection of claim 7 as allegedly being indefinite under 35 U.S.C. §112, second paragraph, with regard to the phrase "the nonporous surface is not part of a capillary space."

3. The rejection of claim 1 and 5 under 35 U.S.C. § 102(b) as allegedly being anticipated by Findlay *et al.*, U.S. Patent 5,514,550.

4. The rejection of claim 3 under 35 U.S.C. § 102(b) as allegedly being anticipated by Findlay *et al.*, U.S. Patent 5,514,550.

5. The rejection of claim 4 under 35 U.S.C. § 102(b) as allegedly being anticipated by Findlay *et al.*, U.S. Patent 5,514,550.

6. The rejection of claim 7 under 35 U.S.C. § 102(b) as allegedly being anticipated by Findlay *et al.*, U.S. Patent 5,514,550.

7. The rejection of claim 1 and 5 under 35 U.S.C. § 102(b) as allegedly being anticipated by Wu, U.S. Patent 5,387,510.

8. The rejection of claim 3 under 35 U.S.C. § 102(b) as allegedly being anticipated by Wu, U.S. Patent 5,387,510.

9. The rejection of claim 4 under 35 U.S.C. § 102(b) as allegedly being anticipated by Wu, U.S. Patent 5,387,510.

10. The rejection of claim 7 under 35 U.S.C. § 102(b) as allegedly being anticipated by Wu, U.S. Patent 5,387,510.

11. The rejection of claim 5 under 35 U.S.C. §103(a), as allegedly being obvious over Findlay *et al.*, U.S. Patent 5,514,550 or Wu, U.S. Patent 5,387,510 in view of Oosta *et al.*, U.S. Patent 5,478,751. As discussed hereinafter, Appellant believes that the rejection is intended to address claim 6, not claim 5.

Argument

1. Rejection of claim 6 under 35 U.S.C. §112, second paragraph

Appellant respectfully traverses the rejection of claim 6 as allegedly being indefinite, and requests that the rejection be withdrawn or reversed.

Claim 6 refers to a nonporous surface that "forms a capillary space between said nonporous surface [of claim 1, from which claim 6 depends] and a second surface spaced at a capillary forming distance from said nonporous surface." Without further explanation or elaboration, the Examiner contends that it is "confusing what structure is contemplated by the claimed second surface and how it interacts with the nonporous surface." Office Action mailed April 7, 2006, page 3. In the Examiner's Answer, the rejection is not further elaborated upon except for a statement on page 8 that the language of claim 6 "does not positively describe the intended structure of the second surface."

Appellant respectfully submits that, to the contrary, the claim could not be more clear in this regard. The claim specifies that the "second surface" is a surface other than the "nonporous surface," and it is spaced at a capillary forming distance from the nonporous surface, thereby forming a capillary space. Such a clearly articulated description of the claimed assay device cannot plausibly be regarded as indefinite under 35 U.S.C. § 112, second paragraph because such description must be "insolubly ambiguous," the accepted standard for indefiniteness. See, e.g., *Ex Parte Hicks*, 2000 WL 33673734, *4 (Bd. Pat. App & Interf.). The Board in *Ex Parte Hicks* offers a useful description of the definiteness standard.

> The threshold for indefiniteness is very high: the claim must be "insolubly ambiguous". . . . If one of skill in the art would understand the scope of the claim when read in light of the specification, then the claim complies with § 112(2). Claims need not be models of clarity. As long as the meaning is discernible, then even if construction is difficult and the result equivocal, the claim is nevertheless definite. Exxon Research & Eng'g Co., 265 F.3d at 1375, 60 USPQ2d at 1276; All Dental Prodx LLC v. Advantage Dental Prods., Inc., 309 F.3d 774, 779-80, 64 USPQ2d 1945, 1949 (Fed. Cir. 2002) (no indefiniteness despite the lack of clarity).

Ex Parte Hicks, 2000 WL 33673734, *4 (Bd. Pat. App & Interf.). Appellant respectfully submits that, in rejecting the claims, the Examiner has not applied the required rigorous standard, and has not met the threshold for establishing indefiniteness.

In view of the foregoing, Applicant respectfully submits that claim 6 reasonably apprises those skilled in the art of the scope of the invention. Because the requirements of 35 U.S.C. § 112, second paragraph, demand no more, Applicant requests that the rejection be withdrawn or reversed.

2. Rejection of claim 7 under 35 U.S.C. §112, second paragraph

Appellant respectfully traverses the rejection of claim 7 as allegedly being indefinite, and requests that the rejection be withdrawn or reversed.

Claim 7 further limits any of claims 1-5 by adding the negative limitation that "the nonporous surface is not part of a capillary space. Such devices are described in the specification as filed, for example on page 32 in the section entitled "Diagnostic Elements Other Than Capillaries."

The Examiner rejects this claim as being indefinite for not further limiting the claims from which claim 7 depends, asserting that "[a]pparently this claim is directed to claiming the absence of a structure (e.g. absence of a capillary space) and is not readily understood." Office Action mailed April 7, 2006, page 3. Thus, the Examiner apparently believes that a negative limitation does not "further limit any one of the previous claims." *Id.* The Examiner's Answer further confuses the rejection at page 8 by stating "[t]his claim does not positively describe the intended structure of the nonporous surface that interacts with the second surface such that it is not part of the capillary space. Appellant notes that no "second surface" is recited in claim 7, and so does not understand the new point raised by the Examiner in the Answer.

Claims may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. *See, e.g., Ex Parte Kirkpatrick*, 1997 WL 33147777 (Bd. Pat. App. Interf.). In this case, the negative limitation clearly indicates that the "nonporous surface" referred to in the claims from which claim 7 depends "is not part of a capillary space." This description of the claimed assay device is not "insolubly ambiguous," and so meets the definiteness standard of 35 U.S.C. § 112, second paragraph.

In view of the foregoing, Applicant respectfully submits that claim 7 reasonably apprises those skilled in the art of the scope of the invention. Because the requirements of 35 U.S.C. § 112, second paragraph, demand no more, Applicant requests that the rejection be withdrawn or reversed.

3. Rejection of claims 1 and 5 under 35 U.S.C. § 102(b) over Findlay *et al.*, U.S. Patent 5,514,550

Appellant respectfully traverses the rejection of claims 1 and 5 as allegedly being anticipated by the Findlay *et al.* patent, and requests that the rejection be withdrawn or reversed.

Claim 1 is directed to assay devices for detecting one or more target ligands comprising (i) a nonporous surface; (ii) one or more particles immobilized to the nonporous surface, where the particles have a size range from 1 nm to 5 μm; and (iii) antibodies or fragments thereof immobilized on the particles, where the antibodies or fragments are capable of binding the target ligand(s).[3]

In contrast, the cited Findlay *et al.* patent is directed to detection of a target ligand (in this case a nucleic acid, see Findlay *et al.*, paragraph bridging columns 3 and 4) using particles having nucleic acids bound to their surfaces that are capable of binding the target ligand. These solid phase-bound nucleic acid "probes" are discussed, for example, in column 4, lines 52-67 of Findlay *et al.* Findlay *et al.* does discuss the use of antibodies, albeit in a single sentence. But this discussion is limited to the use of antibodies only as a detectable label, and not for detection of an analyte of interest. For example, Findlay *et al.* states at column 7, lines 15-26 (emphasis added):

> The present invention also encompasses a method for using the test article described herein to detect a predetermined nucleic acid. The general description of the method is provided above. In one embodiment, the test article is used in a sandwich hybridization assay where a second probe is used to provide detection

[3] Claim 5 depends from claim 1, further providing that the particles are selected from the group consisting of latex particles, silica particles, zirconia particles, alumina particles, titania particles, ceria particles, metal sol particles, and polystyrene particles. Claims 1 and 5 stand or fall together with respect to the rejection based upon the Findlay *et al.* patent. The Examiner addresses the specific particle materials in the Office Action mailed April 7, 2006, page 4.

> of the resulting three-part hybrid. This second probe is also complementary to the predetermined nucleic acid, and contains a moiety which provides detection in some manner (as discussed above). Preferably, the second probe is labeled with avidin, biotin, antibody, antigen, hapten, lectin, sugar (or another specific binding moiety), or other detectable moieties described below.

The Examiner bases the rejection on the assertion that "the instant claim language only requires the presence of antibodies or fragments bound to a nonporous surface" (Office Action mailed October 25, 2006, page 4), and that "Findlay et al. does teach in column 7 lines 23-27 the use of antibodies as part of the target ligand detection" (Examiner's Answer, page 8, last paragraph).

But present claim 1 is directed to "an assay device for detecting one or more target ligands in a sample," and the device as claimed comprises (i) a nonporous surface, (ii) antibodies or fragments thereof immobilized upon particles immobilized to the surface, where the antibodies are "capable of binding said one or more target ligands." In contrast, the antibodies disclosed in the Findlay *et al.* patent are never capable of binding a target ligand. According to Findlay *et al.*, a second nucleic acid probe binds the target ligand. While the second nucleic acid may comprise an antibody that acts as a detectable label, that antibody is not capable of binding said one or more target ligands.

Appellant notes that the rejection is premised on anticipation of the present invention; thus, Findlay *et al.* must teach every element of the present claims. Claim 1 requires a specific structure: antibodies or fragments thereof capable of binding one or more target ligands immobilized on particles. As indicated in the section of Findlay *et al.* quoted above, the Findlay *et al.* device would have the following structure: particle → first probe nucleic acid → target ligand (nucleic acid of interest) → second probe nucleic acid → detectable moiety (antibody not capable of binding the target ligand). No structure corresponding to the antibodies of the present claims is contemplated in the Findlay *et al.* patent.

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. The devices disclosed in the Findlay *et al.* patent are structurally different from those of the present claims. Appellant respectfully submits that, because the cited patents do not provide each and every element set forth in the claims, no *prima facie* case of anticipation has been established, and requests that the rejection be withdrawn or reversed.

4. Rejection of claim 3 under 35 U.S.C. § 102(b) over Findlay *et al.*, U.S. Patent 5,514,550

Appellant respectfully traverses the rejection of claim 3 as allegedly being anticipated by the Findlay *et al.* patent, and requests that the rejection be withdrawn or reversed.

Claim 3 depends from claim 1, and so contains all of the limitations of claim 1. As discussed above, claim 1 requires (i) a nonporous surface; (ii) one or more particles immobilized to the nonporous surface, where the particles have a size range from 1 nm to 5 μm; and (iii) antibodies or fragments thereof immobilized on the particles, where the antibodies or fragments are capable of binding the target ligand(s). The devices disclosed in the Findlay *et al.* patent contain no structure corresponding to antibodies or fragments thereof capable of binding one or more target ligands immobilized on particles.

In addition, claim 3 adds an additional limitation: that the surface to which the particles are immobilized is "a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from said surface."

The Examiner has based the rejection of claim 3 on an assertion that the particles that are specifically recited in claim 1 also correspond to the "depressions and/or protrusions" of the surface itself. Office Action mailed April 7, 2006, page 4 ("The claimed protrusions extending between 1 microns to 0.5 mm has been read on the taught immobilized particles"). Appellant noted previously that the claims unambiguously distinguish between the particles comprising antibodies or fragments thereof immobilized on the nonporous surface on one hand, and the depressions and/or protrusions extending between 1 nm and 0.5 mm from the nonporous surface on the other, and that, according to the Examiner's interpretation of the claims in which the particles are the protrusions, the additional limitations recited in claims 3 and 4 become superfluous, and so the Examiner's interpretation cannot be correct.

The Examiner now modifies this rejection by stating that "the nonporous surface taught by Findlay et al. would have been expected to have at least one depression or protrusion from the surface in the claimed ra[n]ge of 1nm to 0.5mm as an artifact of the manufacturing process." Examiner's Answer, page 9, second full paragraph. Moreover, as the Findlay *et al.* patent is

silent on the point, it is presumed that the Examiner is relying on such depressions or protrusions being an inherent feature of the devices of Findlay *et al.*

Appellant respectfully submits that this is nothing more than conjecture on the part of the Examiner, and is unsupported by any evidence of record. Such depressions or protrusions are not necessarily present in the devices of Findlay *et al.*, and conjecture to the contrary cannot support the Examiner's suggested anticipation rejection. *See, e.g., Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 USPQ2d 1746, 1749-50 (Fed.Cir.1991). (Anticipation based on an inherency argument requires that the missing claim elements must necessarily be present in the prior art).

Applicant respectfully submits that because the cited patents do not provide each and every element set forth in the claims, no *prima facie* case of anticipation has been established, and requests that the rejection be withdrawn or reversed.

5. Rejection of claim 4 under 35 U.S.C. § 102(b) over Findlay *et al.*, U.S. Patent 5,514,550

Appellant respectfully traverses the rejection of claim 4 as allegedly being anticipated by the Findlay *et al.* patent, and requests that the rejection be withdrawn or reversed.

Claim 4 depends from claim 3, and so contains all of the limitations of both claims 1 and 3. As discussed above, the devices disclosed in the Findlay *et al.* patent are structurally different from those of the present claims, and contain no structure corresponding to the antibodies or fragments thereof capable of binding one or more target ligands immobilized on particles as recited in claim 1. The devices disclosed in the Findlay *et al.* patent also contain no structure corresponding to the textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from said surface recited in claim 3.

Claim 4 further provides that "one or more of said particles are entrapped within depressions and/or between protrusions on the textured surface." Appellant noted previously that nothing in the Examiner's statement of rejection indicates where such a teaching of entrapping one or more particles "within depressions and/or between protrusions on the textured surface" may be found in the Findlay *et al.* patent. Because the Examiner has the initial burden of establishing a *prima facie* case of anticipation by pointing out where all of the claim

limitations appear in a single reference, the Examiner's failure to address the limitations of claim 4 cannot establish a *prima facie* case of anticipation of that claim.

The Examiner now modifies this rejection by stating that "it would have been expected for at least one particle to be bound on the artefact." Examiner's Answer, page 9, final full paragraph. Again, as the Findlay *et al.* patent is silent on the point, it is presumed that the Examiner is relying on such depressions or protrusions being an inherent feature of the devices of Findlay *et al.*

Appellant notes that the Examiner's comments do not indicate that any particles are entrapped within depressions and/or between protrusions on the textured surface, as required by claim 4. Moreover, Appellant respectfully submits that the Examiner's comments are nothing more than conjecture on the part of the Examiner, and are unsupported by any evidence of record. Entrapment of particles within depressions and/or between protrusions on a textured surface is not necessarily present in the devices of Findlay *et al.*, and conjecture to the contrary cannot support the Examiner's suggested anticipation rejection. *See, e.g., Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 USPQ2d 1746, 1749-50 (Fed.Cir.1991).

Applicant respectfully submits that because the cited patents do not provide each and every element set forth in the claims, no *prima facie* case of anticipation has been established, and requests that the rejection be withdrawn or reversed.

6. Rejection of claim 7 under 35 U.S.C. § 102(b) over Findlay *et al.*, U.S. Patent 5,514,550

Appellant respectfully traverses the rejection of claim 6 as allegedly being anticipated by the Findlay *et al.* patent, and requests that the rejection be withdrawn or reversed.

Claim 7 depends ultimately from claim 1, and so contains all of the limitations of claim 1. As discussed above, claim 1 requires (i) a nonporous surface; (ii) one or more particles immobilized to the nonporous surface, where the particles have a size range from 1 nm to 5 μm; and (iii) antibodies or fragments thereof immobilized on the particles, where the antibodies or fragments are capable of binding the target ligand(s). The devices disclosed in the Findlay et al. patent contain no structure corresponding to antibodies or fragments thereof capable of binding one or more target ligands immobilized on particles.

Claim 7 further provides that "said nonporous surface is not part of a capillary space."

Nothing in the Examiner's statement of rejection or in the Examiner's Answer indicates where such a teaching may be found in the Findlay *et al.* patent. Because the Examiner has the initial burden of establishing a *prima facie* case of anticipation by pointing out where all of the claim limitations appear in a single reference, the Examiner's failure to address the limitations of claim 4 cannot establish a *prima facie* case of anticipation of that claim.

Applicant respectfully submits that because the cited patents do not provide each and every element set forth in the claims, no *prima facie* case of anticipation has been established, and requests that the rejection be withdrawn or reversed.

7. Rejection of claims 1 and 5 under 35 U.S.C. § 102(b) over Wu, U.S. Patent 5,387,510

Appellant respectfully traverses the rejection of claims 1 and 5 as allegedly being anticipated by the Wu patent, and requests that the rejection be withdrawn or reversed.

Claim 1 is directed to assay devices for detecting one or more target ligands comprising (i) a nonporous surface; (ii) one or more particles immobilized to the nonporous surface, where the particles have a size range from 1 nm to 5 μm; and (iii) antibodies or fragments thereof immobilized on the particles, where the antibodies or fragments are capable of binding the target ligand(s).[4]

Like the Findlay *et al.* patent, the cited the Wu patent is directed to detection of a target ligand (in this case a nucleic acid, see Wu, Abstract) using particles having nucleic acids bound to their surfaces that are capable of binding the target ligand. These solid phase-bound nucleic acid "probes" are discussed, for example, in column 2, lines 57-65 of Wu.

[4] Claim 5 depends from claim 1, further providing that the particles are selected from the group consisting of latex particles, silica particles, zirconia particles, alumina particles, titania particles, ceria particles, metal sol particles, and polystyrene particles. Claims 1 and 5 stand or fall together with respect to the rejection based upon the Wu patent. The Examiner addresses the specific particle materials in the Office Action mailed April 7, 2006, paragraph bridging pages 4 and 5.

And, like the Findlay *et al.* patent, the Wu patent does discuss the use of antibodies, again in a single sentence. And again, this discussion is limited to the use of antibodies only as a detectable label. For example, Wu states at column 11, lines 45-51 (emphasis added):

> In a preferred embodiment, one of the primers is labeled with a specific binding ligand such as biotin, an antibody or lectin. The labeled primer provides (through amplification) an amplified target nucleic acid which has the specific binding ligand attached. This amplified nucleic acid is detected using a detectably labeled receptor for specific binding ligand.

The Examiner bases the rejection on the assertion that "the instant claim language only requires the presence of antibodies or fragments bound to a nonporous surface" (Office Action mailed October 25, 2006, page 4), and that "Wu et al. teach in column 11 lines 45-47 the use of antibodies as part of the target ligand detection" (Examiner's Answer, page 10, first full paragraph). As in the case of the rejection based on Findlay *et al.*, his assertion, however, fails to consider the plain language of the claims.

Present claim 1 is directed to "an assay device for detecting one or more target ligands in a sample," and the device as claimed comprises (i) a nonporous surface, (ii) antibodies or fragments thereof immobilized upon particles immobilized to the surface, where the antibodies are "capable of binding said one or more target ligands." In contrast, the antibodies disclosed in the Wu patent are never capable of binding a target ligand. According to Wu, a nucleic acid primer binds the target ligand. While the nucleic acid primer may comprise an antibody that acts as a detectable label, that antibody is not capable of binding said one or more target ligands. No structure corresponding to the antibodies of the present claims is described in the Wu patent.

Appellant notes that the rejection is premised on anticipation of the present invention; thus, Wu must teach every element of the present claims. Claim 1 requires a specific structure: antibodies or fragments thereof capable of binding one or more target ligands immobilized on particles. As indicated in the section of Wu quoted above, the Wu device would have the following structure: particle → first primer nucleic acid → target ligand (nucleic acid of interest) → second primer acid → detectable moiety (antibody not capable of binding the target ligand). No structure corresponding to the antibodies of the present claims is contemplated in the Findlay *et al.* patent.

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. The devices disclosed in the Wu patent are structurally different from those of the present claims. Appellant respectfully submits that, because the cited patents do not provide each and every element set forth in the claims, no *prima facie* case of anticipation has been established, and requests that the rejection be withdrawn or reversed.

8. Rejection of claim 3 under 35 U.S.C. § 102(b) over Wu, U.S. Patent 5,387,510

Appellant respectfully traverses the rejection of claim 3 as allegedly being anticipated by the Wu patent, and requests that the rejection be withdrawn or reversed.

Claim 3 depends from claim 1, and so contains all of the limitations of claim 1. As discussed above, claim 1 requires (i) a nonporous surface; (ii) one or more particles immobilized to the nonporous surface, where the particles have a size range from 1 nm to 5 μm; and (iii) antibodies or fragments thereof immobilized on the particles, where the antibodies or fragments are capable of binding the target ligand(s). The devices disclosed in the Wu patent contain no structure corresponding to antibodies or fragments thereof capable of binding one or more target ligands immobilized on particles.

In addition, claim 3 adds an additional limitation: that the surface to which the particles are immobilized is "a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from said surface."

The Examiner bases the rejection of claim 3 on an assertion that the particles that are specifically recited in claim 1 also correspond to the "depressions and/or protrusions" of the surface itself. Office Action mailed April 7, 2006, page 5 ("The claimed protrusions extending between 1 microns to 0.5 mm has been read on the taught immobilized particles").

Appellant noted previously that the claims unambiguously distinguish between the particles comprising antibodies or fragments thereof immobilized on the nonporous surface on one hand, and the depressions and/or protrusions extending between 1 nm and 0.5 mm from the nonporous surface on the other, and that, according to the Examiner's interpretation of the claims in which the particles are the protrusions, the additional limitations recited in claims 3 and 4 become superfluous, and so the Examiner's interpretation cannot be correct.

The Examiner now modifies this rejection by stating that "the nonporous surface taught by Wu et al. would have been expected to have at least one depression or protrusion from the surface in the claimed ra[n]ge of 1nm to 0.5mm as an artifact of the manufacturing process." Examiner's Answer, paragraph bridging pages 10 and 11. Moreover, as the Findlay *et al.* patent is silent on the point, it is presumed that the Examiner is relying on such depressions or protrusions being an inherent feature of the devices of Findlay *et al.*

Appellant respectfully submits that this is nothing more than conjecture on the part of the Examiner, and is unsupported by any evidence of record. Such depressions or protrusions are not necessarily present in the devices of Wu, and conjecture to the contrary cannot support the Examiner's suggested anticipation rejection. *See, e.g., Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 USPQ2d 1746, 1749-50 (Fed.Cir.1991). (Anticipation based on an inherency argument requires that the missing claim elements must necessarily be present in the prior art).

Applicant respectfully submits that because the cited patents do not provide each and every element set forth in the claims, no *prima facie* case of anticipation has been established, and requests that the rejection be withdrawn or reversed.

9. Rejection of claim 4 under 35 U.S.C. § 102(b) over Wu, U.S. Patent 5,387,510

Appellant respectfully traverses the rejection of claim 4 as allegedly being anticipated by the Wu patent, and requests that the rejection be withdrawn or reversed.

Claim 4 depends from claim 3, and so contains all of the limitations of both claims 1 and 3. As discussed above, the devices disclosed in the Wu patent are structurally different from those of the present claims, and contain no structure corresponding to the antibodies or fragments thereof capable of binding one or more target ligands immobilized on particles as recited in claim 1. The devices disclosed in the Wu patent also contain no structure corresponding to the textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from said surface recited in claim 3.

Claim 4 further provides that "one or more of said particles are entrapped within depressions and/or between protrusions on the textured surface." Appellant noted previously

that nothing in the Examiner's statement of rejection indicates where such a teaching of entrapping one or more particles "within depressions and/or between protrusions on the textured surface" may be found in the Wu patent. Because the Examiner has the initial burden of establishing a *prima facie* case of anticipation by pointing out where all of the claim limitations appear in a single reference, the Examiner's failure to address the limitations of claim 4 cannot establish a *prima facie* case of anticipation of that claim.

The Examiner now modifies this rejection by stating that "[i]t would have been expected for at least one particle to be bound on the artefact." Examiner's Answer, page 11, first full paragraph. Again, as the Wu patent is silent on the point, it is presumed that the Examiner is relying on such depressions or protrusions being an inherent feature of the devices of Wu.

Appellant notes that the Examiner's comments do not indicate that any particles are entrapped within depressions and/or between protrusions on the textured surface, as required by claim 4. Moreover, Appellant respectfully submits that the Examiner's comments are nothing more than conjecture on the part of the Examiner, and are unsupported by any evidence of record. Entrapment of particles within depressions and/or between protrusions on a textured surface is not necessarily present in the devices of Wu, and conjecture to the contrary cannot support the Examiner's suggested anticipation rejection. *See, e.g., Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 USPQ2d 1746, 1749-50 (Fed.Cir.1991).

Applicant respectfully submits that because the cited patents do not provide each and every element set forth in the claims, no *prima facie* case of anticipation has been established, and requests that the rejection be withdrawn or reversed.

10. Rejection of claim 7 under 35 U.S.C. § 102(b) over Wu, U.S. Patent 5,387,510

Appellant respectfully traverses the rejection of claim 6 as allegedly being anticipated by the Wu patent, and requests that the rejection be withdrawn or reversed.

Claim 7 depends ultimately from claim 1, and so contains all of the limitations of claim 1. As discussed above, claim 1 requires (i) a nonporous surface; (ii) one or more particles immobilized to the nonporous surface, where the particles have a size range from 1 nm to 5 μm; and (iii) antibodies or fragments thereof immobilized on the particles, where the antibodies or

fragments are capable of binding the target ligand(s). The devices disclosed in the Wu patent contain no structure corresponding to antibodies or fragments thereof capable of binding one or more target ligands immobilized on particles.

Claim 7 further provides that "said nonporous surface is not part of a capillary space."

Nothing in the Examiner's statement of rejection or in the Examiner's Answer indicates where such a teaching may be found in the Wu patent. Because the Examiner has the initial burden of establishing a *prima facie* case of anticipation by pointing out where all of the claim limitations appear in a single reference, the Examiner's failure to address the limitations of claim 4 cannot establish a *prima facie* case of anticipation of that claim.

Applicant respectfully submits that because the cited patents do not provide each and every element set forth in the claims, no *prima facie* case of anticipation has been established, and requests that the rejection be withdrawn or reversed.

11. Rejection of claim 5 under 35 U.S.C. § 103(a) over Findlay *et al.*, U.S. Patent 5,514,550 or Wu, U.S. Patent 5,387,510 in view of Oosta *et al.*, U.S. Patent 5,478,751

Appellant respectfully traverses the rejection of claim 5 as allegedly being obvious over either the Findlay *et al.* or Wu patent in view of Oosta *et al.*, and requests that the rejection be withdrawn or reversed.

This is a new ground of rejection presented for the first time in the Examiner's Answer. As an initial matter, Appellant notes that the rejection refers to claim 5. Examiner's Answer, page 6, last paragraph. Appellant believes that the rejection is intended to refer to claim 6, which provides that "said nonporous surface forms a capillary space between said nonporous surface and a second surface spaced at a capillary forming distance from said nonporous surface." Examiner's Answer, paragraph bridging pages 9 and 10. Appellant will refer to claim 6 rather than claim 5 in the rebuttal to the rejection below.

The Oosta *et al.* patent has an earliest filing date of December 29, 1993, and is prior art to the present invention only to the extent that the present claims are not entitled to an earlier claimed priority. The Examiner asserts that claim 6 is not entitled to that claimed priority "because the parent patents 6,156,270, 6,143,576, and 6,271,040 does not contain the presently

claimed 'nonporous' surface." Examiner's Answer, page 5. Why the Examiner has not addressed U.S. Patent 5,458,852, filed May 21, 1992, or U.S. Patent Application 08/065,528, filed May 19, 1993, to each of which the present application claims priority, is unclear. By failing to properly consider the sufficiency of all the cited applications to which priority is claimed, Appellant respectfully submits the Examiner's obviousness is legally insufficient.

As Appellant described in some detail in an office action response mailed August 2, 2006, U.S. Patent 5,458,852 states, for example in column 2, lines 4-7, that the described devices "do not use bibulous or porous materials, such as membranes and the like as substrates for the immobilization of reagents or to control the flow of the reagents through the device . . . . The devices of the current invention circumvent these membrane associated problems by the use of defined surfaces, including grooved surfaces, capillarity, time gates, novel capillary means, including channels and novel fluid flow control means alone or in various combinations, all of which are constructed from non-absorbent materials." Thus, even the earliest priority document "contains the presently claimed 'nonporous' surface."

Additional exemplary support for the present claims may be found in U.S. Patent Application 08/065,528 as follows:

An assay device for detecting one or more target ligands in a sample, comprising	page 1, lines 5-8
a nonporous surface	page 3, lines 1-4
one or more particles immobilized to said surface	page 23, line 28 – page 24, line 34
wherein said particles comprise antibodies or fragments thereof immobilized thereon capable of binding said one or more target ligands	page 23, line 28 – page 24, line 34, and page 5, lines 4-10
wherein said particle size range is from 1 nm to 5 μm	page 23, lines 28-37
wherein said nonporous surface forms a capillary space between said nonporous surface and a second surface spaced at a capillary forming distance from said nonporous surface	page 22, line 34 – page 23, line 1

Appellant respectfully submits that, when properly considered, the present claims are entitled to an effective filing date of at least May 19, 1993, and that the Oosta *et al.* patent, having an earliest filing date of December 29, 1993, is not citable as prior art against the present claims. Because no *prima facie* case of obviousness has been established, Appellant requests that the rejection be withdrawn or reversed.

Conclusion

For the reasons discussed above, Appellant respectfully submits that claims 1 and 3-7 are in condition for allowance, and respectfully request that the rejections be withdrawn or reversed, and that the claims be allowed to issue.

Respectfully submitted,

Date: 09/24/2007

By: _____
Richard J. Warburg. Reg. No. 32,327
By Barry Wilson, Reg. No. 39,431

FOLEY & LARDNER
P.O. Box 80278
San Diego, CA 92138-0278
(858) 847-6700 (Voice)
(858) 792-6773 (Fax)

Appendix A: Text of the Claims Involved in the Appeal

1. (Previously presented) An assay device for detecting one or more target ligands in a sample, comprising:

a nonporous surface comprising one or more particles immobilized to said surface, wherein said particles comprise antibodies or fragments thereof immobilized thereon capable of binding said one or more target ligands wherein said particle size range is from 1 nm to 5 μm.

2. (Cancelled)

3. (Original) An assay device according to claim 1, wherein said surface is a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from said surface.

4. (Original) An assay device according to claim 3, wherein one or more of said particles are entrapped within depressions and/or between protrusions on the textured surface.

5. (Original) An assay device according to claim 1, wherein said particles are selected from the group consisting of latex particles, silica particles, zirconia particles, alumina particles, titania particles, ceria particles, metal sol particles, and polystyrene particles.

6. (Original) An assay device according to any one of claims 1-5, wherein said nonporous surface forms a capillary space between said nonporous surface and a second surface spaced at a capillary forming distance from said nonporous surface.

7. (Original) An assay device according to any one of claims 1-5, wherein said nonporous surface is not part of a capillary space.